APR 1 6 2002

DYmedix, Inc.

K020468

Summary of Safety and Effectiveness

Company Name:	DYmedix, Inc. 3989 Central Ave. NE Suite 116 Minneapolis, MN 55421
Contact:	Peter Stasz, CEO
Phone:	(763) 789-8280
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Summary Date:	April 15, 2002
Trade Name:	Chin Electrode
Common Name:	Cutaneous Electrode
Classification Name:	Predicate electrodes have been found substantially equivalent to 882.1320, Cutaneous Electrode, Class II, GXY.

Predicate Device:

510(k) Number:	K931430
Manufacture:	MEDICOTEST, Inc.
Trade Name:	Neuroline Electrodes
Product Code:	BZQ

1.0 Description of the Chin Electrode

During the evaluation of sleep disorders, a variety of electrodes and sensors supporting recording of various parameters are attached to the patient. Measurement of electromyography (EMG) signals at the chin can be performed. Clinicians can place discrete surface electrodes on the chin to acquire the EMG signal.

The Chin Electrode is provided as a convenience to the sleep clinician. The Chin Electrode consists of three cutaneous electrodes within one assembly. In clinical application, the Chin Electrode is placed on the subject's chin. The lead wires are

connected to the user's sleep recording instrumentation. The user's sleep recording instrument provides the electrical isolation for patient safety.

2.0 Intended Use of the Chin Electrode

The DYmedix Inc. Chin Electrode is a cutaneous electromyography (EMG) electrode. The Chin Electrode supports EMG monitoring of muscles in the chin and other surface EMG monitoring locations as directed by a physician during sleep studies.

3.0 Technological Characteristics

The technology of the Chin Electrode is equivalent to other cutaneous electrodes. A conductive gel, as part of the Chin Electrode assembly conducts the EMG signal to an Ag/AgCl contact in the electrodes. The Chin Electrode is connected to the user's sleep recording instrument for signal amplification and conditioning.

The skin contact materials were qualified by ISO 10993 biocompatibility or have a history of safe use in other medical devices. The Chin Electrode lead wires have recessed sockets. The lead wires comply with the FDA requirement for safe sensor lead wires, 21 CFR Part 898.

4.0 Data Summary

Laboratory data are presented to demonstrate performance of the Chin Electrode. A Certification of Conformance to the FDA Performance Standard for Lead Wires and Patient Cables, 21 CFR Part 898 and ISO 10993 is provided.

5.0 Conclusions

The laboratory data and certification support the conclusion of the safety and effectiveness the Chin Electrode.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DYmedix, Inc.
c/o Mr. Gary Syring
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton, Wisconsin 53589

APR 1 6 2002

Re: K020468
Trade/Device Name: Chin Electrode
Regulation Number: 882.1320
Regulation Name: Cutaneous Electrode
Regulatory Class: II
Product Code: GXY
Dated: February 11, 2002
Received: February 12, 2002

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020468

Device Name: Chin Electrode

Indications For Use:

The DYmedix Inc. Chin Electrode is a cutaneous electromyography (EMG) electrode. The Chin Electrode supports EMG monitoring of muscles in the chin and other surface EMG monitoring locations as directed by a physician during sleep studies.

(PLEASE: DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020468